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Cervical Cap: Newest Birth Control Choice

by Marian Segal

The search for birth control began thousands of years ago; records extending over 4 millennia catalog pastes, gums and gels intended to waylay the voyage of sperm to egg. Today, we're still at it, persisting in our efforts to build a better barrier to conception. The Food and Drug Administration's approval in May 1988 of the Prentif Cervical Cap, manufactured by the British firm of Lamberts (Dalston) Ltd., provides women with one more birth control option.

And, in the opinion of Lillian Yin, Ph.D., director of FDA's division of obstetrics and gynecology, ear, nose, throat, and dental devices, the more options available for women who practice birth control, the better. "The cervical cap may not be perfect," says Yin, "but it provides women with another choice; it is important for each woman to use a method she finds convenient and comfortable."

The cervical cap is a small rubber device that is inserted into the vagina to block sperm from entering the cervix (the opening to the uterus). Like the diaphragm, the cap is a prescription device that comes in several sizes and must be fitted by a trained health worker. Also like the diaphragm, the cap is used with a spermicide. The two devices offer virtually the same degree of protection; both have an overall effectiveness rate of about 83 percent. That means, generally, that in a large population of women, 83 percent who use a cervical cap or diaphragm will not become pregnant within a year. So what's new and different about the cervical cap that women might find more desirable than the diaphragm?

The newly approved cervical cap is available in four sizes. All are smaller than the diaphragm (shown for comparison), which also comes in several sizes.

OLD IDEA IN A NEW FORM

Actually, not much about the cap is new. In fact, invention of the modern rubber cervical cap by the German physician Frederich A. Wilde in 1838 predates that of the diaphragm by more than 40 years. And, in one form or another, the cap has existed for thousands of years, constructed from materials as varied as crocodile dung molded to cover the cervix (described in an Egyptian medical papyrus dating from 1852 B.C.) to a squeezed-out lemon half placed over the cervix, purportedly promoted by the 18th century rake Casanova. Not only did the lemon rind provide a barrier to the cervix, but the acidic juice served as a spermicide.

So the cap is even older than the diaphragm. It is also different from the diaphragm in some notable ways. The flexible thimble-

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shaped latex cap, about 1½ inches in diameter, fits tightly over the cervix and is held in place by suction. The larger diaphragm, about 3 inches wide, is placed between the pubic bone and the vaginal wall and kept in place by tension. A spermicidal cream or gel is used with both devices, but the cap requires less of such substances and is, therefore, thought by some to be less messy than the diaphragm. The major advantage the cap offers over the diaphragm, however, is a greater degree of sexual spontaneity. While the diaphragm must be removed after 24 hours, the cap can stay in place up to 48 hours. Also, the cap does not require additional applications of spermicide with each act of intercourse, as does the diaphragm.

Some women report that the cap is more difficult to use than the diaphragm. The cap containing spermicide is inserted into the vagina by grasping the cap, dome down, between two fingers of one hand and compressing the rim. The cap is pushed as far as it will go along the back wall of the vaginal canal, and then the rim must be pressed around the cervix until it seals. The cap is removed by tilting the rim away from the cervix, thus breaking the suction; or it can be grasped between two fingers and pulled downward. Thus, insertion and removal require manual dexterity and knowledge of anatomy, and may be difficult for some women, even after detailed instruction.

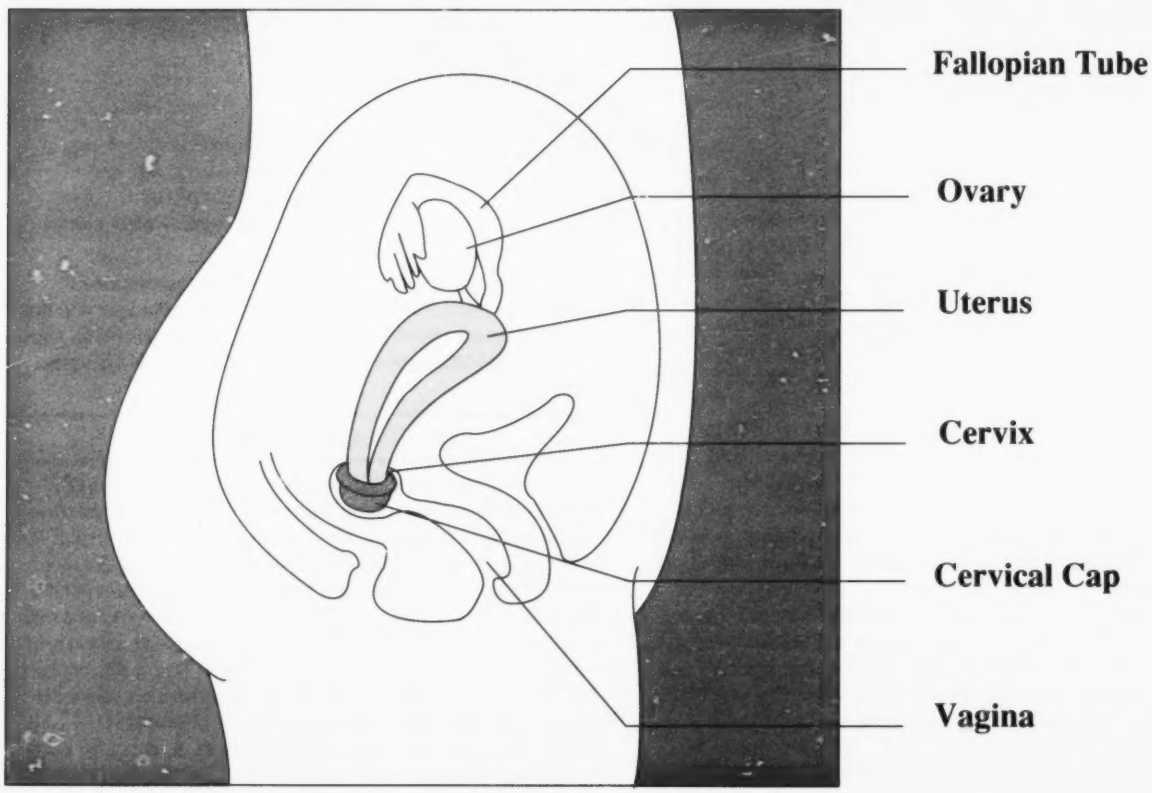
This was not the case with one Lady R.B. of Great Britain, however. Interviewed by Barbara Seaman and Gideon Seaman, M.D., authors of *Women and the Crisis in Sex Hormones*, published in 1977, Lady R.B. extolled the virtues of the cap, as she saw them:

"Taking it out is a little trickier than putting it in, actually; you have to tilt the rim away from the cervix to break the suction. Putting it in is, well, no harder than slipping a thimble on your finger with your eyes closed. Once while we were visiting the States I misplaced it. I had to get a diaphragm temporarily. Too springy for me—it was always bouncing away and rolling across the bathroom floor. I didn't like having to muss with the jelly all the time, or taking it in and out whenever we made love."

The cervical cap was introduced in the United States early in the 20th century, and the American family planning pioneer Margaret Sanger promoted it in her 1914 pamphlet, *Family Limitation*. Its use in this country waned in favor of the diaphragm, though, most likely because Sanger later expressed a preference for the diaphragm, viewing it as less physician-dependent and easier to use than the cap. In her 1987 book, *The Complete Cervical Cap Guide*, Rebecca Chalker explains that in Victorian England it was considered "inappropriate for women to deal with genital matters." Thus, women of means would have their physicians insert the cap at the end of their menstrual period each month and remove it again before the next one. This practice gained a reputation for the cap as being "physician-controlled." The diaphragm, on the other hand, was used widely in Holland, where it was viewed by the Dutch as easily handled by women themselves.

Chalker notes that "from the mid-1930s on, the term 'cervical cap' all but disappeared from the contraceptive lexicon in the United States. Throughout the 1940s and 1950s couples depended heavily upon condoms and withdrawal or, if they sought the advice of a physician, the diaphragm."

It's not surprising, then, that the little-used cap was not "grandfathered" into the system, as were the condom and diaphragm, when FDA began to require pre-market approval for medical devices in the late 1970s. Under the Medical Device Amendments of 1976, cervical caps used as contraceptives were categorized as Class III devices, meaning their safety and effectiveness had to be proved before they could be marketed.



Comparing Contraceptives

	Overall Effectiveness Rate
Oral contraceptive (with estrogen and progestin)	**97%**
Intrauterine device	**94%**
Diaphragm	**83.3%**
Cervical cap	**82.6%**

Overall effectiveness rate takes into account pregnancies that result from both user failure (not using the method or using it improperly) and method failure (fault with the method itself). The rates represent the percentage of women who use that method for one year and do not get pregnant.

Statistics on effectiveness of the cervical cap and the diaphragm are unpublished data from Dr. Gerald S. Bernstein, professor of obstetrics and gynecology, University of Southern California School of Medicine. Those on oral contraceptives and intrauterine devices are from* Studies in Family Planning, *September-October 1987.

U.S. INTEREST REVIVES

It was the discourse on the cervical cap in Seaman and Seaman's book that was probably most instrumental in renewing interest in the device in the United States. The book appeared at a time of growing concern about serious side effects some women experienced with the newer, high-tech contraceptives—intrauterine devices (IUDs) and oral contraceptives (commonly referred to as "the pill"). Major complications of the pill include blood clots in the legs, pelvis, lungs, heart or brain; stroke; heart attack; and hypertension. These complications are rare, however, and occur primarily in women who smoke, who are over 35, or who have other health problems such as diabetes or vascular disease or a family history of those diseases. Other problems with the pill include headaches, eye problems, acne, depression, nausea, and weight gain.

On the other hand, there are some non-contraceptive health benefits associated with use of birth control pills. These include protection against pelvic inflammatory disease, which is a major cause of infertility in women, and protection against ovarian and endometrial cancer. Furthermore, women using the pill have more regular menstrual periods, often with less bleeding and less discomfort. Use of the pill may also help clear up acne and decrease the risk of developing fibrocystic breast disease and iron-deficiency anemia.

Major complications of IUDs are embedding of the device in the uterus, perforation of the cervix or uterus, and pelvic inflammatory disease, which may require hospitalization and can, in some instances, lead to sterility or even death. (These dangers were brought to the public's attention most forcefully several years ago in connection with the Dalkon Shield. The multitude of serious problems that resulted from use of this IUD, which was marketed before the 1976 medical device legislation, dramatically illustrated the need for careful pre-market testing of medical devices.) Other possible side effects of IUDs are bleeding and pain. In some cases, the device is difficult to remove, and in some women it is spontaneously expelled from the uterus.

The only non-contraceptive health benefit related to use of the IUD is decreased menstrual bleeding and less painful periods in women using a particular type of IUD in which the hormone progestin is infused into the uterus.

CAP TESTING

Women activists in the late 1970s began a campaign for FDA approval of the cap, which many saw as having important advantages over the pill, the IUD, and other methods of contraception, including the diaphragm. At that time, Secretary of Health, Education, and Welfare Patricia Harris requested that FDA and the National Institutes of Health (NIH) help expedite testing the cap and making it available to women. FDA worked with women's groups to help them develop study protocols and issued nearly 100 "investigational device exemptions," under which approximately 50,000 women were fitted with a cervical cap or a diaphragm by a trained professional or lay health worker. The women's groups obtained informed consent from the study participants and submitted to FDA the data they collected on safety and efficacy of the cap.

The largest single study was funded by NIH's National Institute of Child Health and Human Development and headed by Gerald S. Bernstein, an obstetrician-gynecologist at the University of Southern California. Involving more than 1,000 women at eight California clinics, the study went from July 1981 to March 1986. The women were randomly assigned to use either the Prentif cervical cap (581 women) or the Ortho diaphragm (572 women). All were given instructions for use and were followed with periodic gynecologic exams and Pap tests. (A Pap test is an examination of cells taken from the cervix. Abnormal cells may indicate cancer or a precancerous condition, but not always; they can also result simply from an infection or other easily treated condition.)

Bernstein's study showed the diaphragm and cervical cap were equally effective in preventing pregnancy. One-year overall pregnancy rates were 17.4 percent for cap users and 16.7 percent for diaphragm users.

Effectiveness rates, however, can be expressed more definitively in terms of "user failures" or "method failures." For instance, a pregnancy that results because the woman left her cervical cap or diaphragm in the dresser drawer is determined to be a user failure. A pregnancy that results despite consistent and

Once Popular IUDs Down but Not Out

While the popularity and availability of the cervical cap are on the rise, the fortunes of another method of contraception—the intrauterine device (IUD)—have waned. Nevertheless, after years of controversy over adverse effects of IUDs and the removal from the market of two widely used models, the once popular device is still available.

Two IUDs are now being sold in the United States. The ParaGard T 380A, approved by FDA in 1984, has been marketed in this country since June 1988 by GynoPharma, Inc., of Somerville, N.J. Label directions for the device, which were appproved in April 1988, state the product is "recommended for women who have had at least one child and are in a stable, mutually monogamous relationship." The patient information for the device notes that ParaGard users with multiple sexual partners are more likely than other women to suffer pelvic inflammatory disease, which can lead to infertility.

Similar to the Tatum T and the Copper 7, which were removed from the market by their manufacturers two years ago, the ParaGard releases copper into the uterus. The copper enhances the contraceptive effectiveness of the device.

The other IUD available to women in the United States is the Progestasert, approved by FDA in 1976 and marketed by Alza Corp., of Palo Alto, Calif. As the release of copper enhances the effectiveness of the ParaGard IUD, so the release of progesterone increases the effectiveness of the Progestasert IUD.

Among other warnings, the labeling for both contraceptives states that women who have or have had pelvic inflammatory disease or a sexually transmitted disease should not use the device. ■

correct use of the method, on the other hand, can be ascribed to method failure. In Bernstein's study, user failure at the end of 12 months was 11.7 percent for the cap and 12.6 percent for the diaphragm. Method failure was 6.4 percent for the cap and 4.6 percent for the diaphragm. (The percentages for method and user failure add up to more than the total overall pregnancy rate for each device because of the statistical methods used in analyzing the data.)

The September-October 1987 issue of *Studies in Family Planning* reports the lowest method failure rate found for oral contraceptives that contain both estrogen and progestin is 0.1 percent, with an overall failure (pregnancy) rate of 3 percent; the lowest method failure rate for the IUD is 1 percent, with an overall pregnancy rate of 6 percent.

DRAWBACKS OF THE CAP

Experience with the cervical cap revealed some drawbacks, both with user convenience and possible health consequences. Of greatest concern was the change in Pap test results from normal to abnormal. In Bernstein's study, 4 percent of women using the cap converted to abnormal results after wearing the cap for three months, compared with 1.7 percent of women using a diaphragm. After the first three months, however, the conversion rates were similar for both devices. Because of this finding, FDA approved the cap with the condition that post-approval studies be conducted to obtain more data on the Pap test results of cap wearers and to try to determine what risk factors may predispose them to cervical cell changes. Also, the directions for the device specify that it is to be prescribed only for women with normal Pap tests and that all users have a repeat test after three months. If the repeat test is positive, the device should no longer be used.

There is no established association between use of the cap and development of toxic shock syndrome (TSS), a rare but sometimes fatal condition that afflicts mainly women. The label warns, however, that, as with any product that blocks the vagina—such as a tampon or a diaphragm—the risk of TSS may be increased. Therefore, women with a history of TSS and those with vaginal or cervical infections are advised not to use the cap. A woman should not wear the cap during a menstrual period or for six weeks after giving birth or having a miscarriage or abortion. The label also warns that use of the cap should be discontinued if the woman or her partner experiences burning or irritation of the genitals.

Some women in the studies had difficulty inserting or removing the cap, and in some it became dislodged occasionally. Also, because the cap comes in only four sizes, some women could not be properly fitted. Some noticed an unpleasant odor with the cap, usually when the device was worn for more than a few days. Removing the cap and cleaning it should alleviate the problem.

The cervical cap adds to the choices of birth control practices available to women and men. It should be remembered that the safest and most effective method for one woman, or couple, may not be the best for another. It is also important to remember that cervical caps and diaphragms may not protect against sexually transmitted diseases, including AIDS. The best barrier against these diseases is the condom—used properly and consistently. Lifestyle and medical history must be carefully considered in determining the contraceptive method that will be best for a given individual. This determination should be made by the woman, or couple, in consultation with a physician who can present the advantages and disadvantages, and risks and benefits of all methods available.

(For more on the risks and benefits of all methods of contraception, see "Comparing Contraceptives" in the May 1985 *FDA Consumer.*) ■

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